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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,662	10/10/2006	Patrick Gerard Johnston	36290-0416-00-US	5029

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EXAMINER	
NATARAJAN, MEERA	
ART UNIT	PAPER NUMBER
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,662	JOHNSTON ET AL.	
	Examiner	Art Unit	
	MEERA NATARAJAN	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-34* is/are pending in the application.

4a) Of the above claim(s) *9-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/26/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, Claims 18-34 and species topoisomerase I inhibitor and colorectal cancer in the reply filed on 04/17/2008 is acknowledged. The traversal is on the ground(s) that Groups I and II do not lack novelty over Allen et al. Applicants argue that Allen et al. does not teach cells which have a p53 mutation as recited in the claims. This is not found persuasive because it is well known in the art that cancer cells typically have p53 mutations and the MCF-7 breast cancer cell line is no exception (see Halder et al., Cancer Research, Vol. 54, pp.2095-2097, 1994 as evidence). The requirement is still deemed proper and is therefore made FINAL.

2. Claims 9-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 04/17/2008.

Claims 18-34 will be examined on the merits.

Claim Objections

3. Claims 23 and 25 are objected to because of the following informalities: The claims recite “according to claim” without reciting an appropriate claim # for which the claim is depending from. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 18-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter

which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

7. The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability, 5) existence of working samples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

8. The claims, as written, are drawn to compositions for gene therapy. The disclosure does not teach gene therapy. Generic nucleic acids are discussed in the specification as encoding antagonists to FAS receptors (p. 13-15). The specification contemplates administering nucleic acids as "binding members," but does not teach any specific nucleic acid. The claims read on using nucleic acids as gene therapy. Gene therapy is still in its infancy and, as such, is very unpredictable, as administration is highly dependent on a number of distinct factors, including the bioavailability of the pharmaceutical formulation, the nature of the condition being treated, and the overall health of the subject. There are many well-documented problems associated with gene therapy, including inefficient gene transfer, host immune response, and the need for tissue-specific targeting (see Chung-Faye *et al.*, Mol Med Today 2000 Feb (6):82-87, especially at p. 86, second column, second paragraph; and Verma, *et al.*, Nature 18 Sep 1987 389:239-242, especially p. 239, third column, first full paragraph). Both Chung-Faye *et al.*, and Verma *et al.*, teach that gene therapy is unpredictable. Moreover, gene therapy, as a means of treatment, is known to be unpredictable. See, for example, Juengst, BMJ 2003 Jun 28;326(7404):1410-1.

9. Moreover, gene therapy against tumors is highly unpredictable as underscored by Crystal (Science. 1995 Oct; 270:404-410) who teaches that in tumor vaccine studies intended to evoke a tumor-directed immune response,

there is no convicining evidence (other than anecdotal case reports) that tumors actually regress, despite the promising observations in experimental animals. In other words, humans are not simply large mice (page 409, column 1). More recently, Tait *et al*. (Clin.Canc.Res., Vol. 5, July 1999, pages 1708-1714) revealed just how unpredictable gene therapy was in the clinical setting. The authors' prior phase I trial of 12 patients with extensive ovarian cancer treated with a retroviral vector expressing the BRCA1 splice variant (LXSN-BRCA1sv) demonsrated vector stability, minimal immune response, gene transfer and expression, and some tumor reduction in the patients (page 1708, column 2, second paragraph). In contrast, the Phase II trial inititiated in pateints with stage III and IV grade ovarian cancer, showed a high preponderance for vector instability (vector was degraded rapidly), a rapid immunological response invoking neutralizing antibodies to the retroviral vector, and no clinical response to the therapy. Although the difference in response to the therapy may be attributed to differences in immunocompetence between the phase I and II patients (page 1712, column 2), the end result seems to indicate that further experimentation is necessary prior to the successful application of DNA vaccines, especially with the regards to cancer therapy.

10. Due to the large quantity of experimentation necessary to determine the efficacy of nucleic acids encoding antagonists to FAS receptors in any species, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to the same, the complex nature of the invention, and the breadth of the claims, which fail to recite any particular nucleic acid and also embrace a broad class of structural fragments and variants, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention directed toward gene therapy.

11. Claims 18-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for a product comprising anti-FAS antibody CH11 (commercially available from UPSTATE BIOTECHNOLOGY) and

Irinotecan (CPT-11), does not reasonably provide enablement for a composition comprising **any** "specific binding members," and/or antibody fragments. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

12. The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability, 5) existence of working samples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

13. The claims recite a pharmaceutical composition comprising (a) a specific binding member which binds to a cell death receptor or a nucleic acid encoding said binding member and (b) a chemotherapeutic agent for the simultaneous, separate or sequential use in the treatment of cancer wherein said cell death receptor is FAS and wherein said chemotherapeutic agent is Irinotecan (CPT11). The nature of the invention is drawn to a composition comprising a "specific binding member" which, according to the disclosure may be any moiety, including, but not limited to a polypeptide, a polynucleotide, a small molecule, an enzyme, an antibody, or a ligand, and a chemotherapeutic agent.

14. "FAS' is defined in the disclosure as the FAS "death receptor," distinguishing it from the FAS ligand (FASL or CD95L). It is also known as TNFR6 and APO-1. The state of the art discloses that inhibitors that bind FAS are well known in the art. For example, the superoxide anion (O_2-) is a naturally occurring inhibitor of FAS and of FAS-mediated cell death (see, i.e. Clement et al., EMBO J. 1996 Jan 15; 15(2):216-225).

15. It is noted that Applicant's one specific anti-FAS antibody claimed, anti-FAS antibody CH11, is commercially available from UPSTATE BIOTECHNOLOGY. Jiang et al., (Hepatology. 1999 Jan;29(1):101-10) teach a

composition comprising anti-FAS antibody CH11, 5-FU, in a buffer (p. 102, column 1, third paragraph; p. 104, column 1, second paragraph) against hepatoma cell lines (liver cancer) (p. 104, column 1, second paragraph).

16. The level of skill of those in the art is high due to the high degree of unpredictability of cancer therapeutics. Applicants refer to generalized prophetic examples in the specification, but no data, beyond the drawings are presented to provide guidance regarding the broadly claimed genus of compositions.

17. Applicants' claims are excessively broad due, in part, to the generic, generalized way in which "specific binding members" and chemotherapeutic agents are recited. Although numerous anti-FAS antibodies are known in the art, Applicant fails to provide any guidance on any antibody other than the anti-FAS CD11 antibody in the disclosure. Applicant also fails to provide any guidance on antibody fragments in the claimed composition. Further, although the intended use of a composition asserted within composition claims is not accorded any patentable weight, Applicant has not provided sufficient guidance in the specification as to whether any of the claimed compositions will work for the intended use in the various cancers of claim 27. However, it is noted that Jiang et al., (*supra*) teach a composition identical to the claimed composition for use in liver cancer (p. 104, column 1, second paragraph).

18. Treatment of cancer in general is at most unpredictable, as underscored by Gura (Science. 1997 Nov 7; 278:1041-1042), who discusses the potential shortcomings of potential anti-cancer agents including extrapolating from *in vitro* to *in vivo* protocols, the problems of drug testing in knockout mice, and problems associated with clonogenic assays. Indeed, since formal screening began in 1955, thousands of drugs have shown activity in either cell or animal models, but only 39 that are used exclusively for chemotherapy, as opposed to supportive care, have won approval from the FDA (Gura, *supra*, p. 1041, column 1) wherein the fundamental problem in drug discovery for cancer is that the model systems are not predictive. All of this underscores the criticality of providing sufficient workable examples and relevant data which are not disclosed in the

specification, particularly in an unpredictable art, such as cancer therapy. As such, undue experimentation is required to practice the claimed invention. The guidance provided by the specification is not commensurate with the claims, as written.

19. Due to the large quantity of experimentation necessary to determine which members of the genus of "specific binding members" are sufficient to comprise a composition also comprising a member of the recited list of chemotherapeutic agents, will be effective in treating cancer, as the recited use, the lack of direction/guidance presented in the specification regarding same, the absence of sufficient working examples directed to same, the complex nature of the invention, the state of the prior art establishing that cancer therapy is unpredictable, and the excessive breadth of the claims, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

20. Claims 18-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a written description rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

21. The claims recite a product comprising (a) a specific binding member which binds to a cell death receptor or a nucleic acid encoding said binding member and (b) a chemotherapeutic agent for the simultaneous, separate or sequential use in the treatment of cancer wherein said cell death receptor is FAS and wherein said chemotherapeutic agent is Irinotecan (CPT11

22. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, states that Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117). A review of the language of the claim indicates that these claims are drawn to a genus, i.e., a genus of "specific binding members," a genus of antibodies, and a genus of antibody fragments.

23. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

24. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states, "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

25. There is a single species of the claimed genus disclosed that is within the scope of the claimed genus, *i.e.* anti-FAS CH11 antibodies. The disclosure of a

single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species that are not further described.

26. In the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus, which is a genus of "specific binding members," a genus of antibodies, and a genus of antibody fragments. One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus. The specification does not clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed (see *Vas-Cath* at page 1116).

27. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 112, Second Paragraph

28. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

29. Claims 18-19, 21, 23-24, 26-28, 30-31, and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "specific binding member" is confusing and unclear. The specification defines the term as "any moiety," which does not adequately define or otherwise clarify or limit what is to be encompassed by the term.

Claim Rejections - 35 USC § 103

30. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

31. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

32. Claims 18-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jiang et al., (Hepatology. 1999 Jan;29(1):101-10), in view of Caligirui et al., (US Patent 6,042,826, 28 March 2000) and Mross et al., (Schweiz Rundsch Med Prax. 2001 Mar 22;90(12):497-510, abstract only).

33. The instant claims are drawn to a product and pharmaceutical composition comprising an anti-FAS antibody or a fragment thereof and a chemotherapeutic agent, wherein the chemotherapeutic agent which is a topoisomerase I inhibitor, Irinotecan (CPT-11), and wherein the antibody is the anti-FAS antibody CH-11 and comprises at least one human constant region.

34. Jiang et al., teach a composition comprising anti-FAS antibody CH11 (which is commercially available from UPSTATE BIOTECHNOLOGY), and the chemotherapeutic 5-FU, in a buffer (p. 102, column 1, third paragraph; p. 104, column 1, second paragraph) against hepatoma cell lines (liver cancer) (p. 104, column 1, second paragraph) (compare claims 18, 19, 23, and 30). Jiang et al., do not teach a binding member comprising at least one human constant region or the chemotherapeutic agent, Irinotecan (also known as CPT-11). These deficiencies are made up for by Caligirui et al., and Mross et al.,

35. Caligirui et al. teach a composition comprising modified anti-FAS CH11 humanized antibodies (column 5, lines 54-67 to column 6, lines 1-44) (compare

claims 18, 19, 23, 24, 30, and 31). Compositions comprising anti-FAS antibodies and chemotherapeutic agents such as cisplatin are taught at column 3, lines 35-41.

36. Mross et al., teach that 5-FU, oxaliplatin, irinotecan, and raltitrexed (Tomudex) are equivalent first-line anti-cancer chemotherapeutic agents (abstract) (compare claims 18, 19, 26, and 33).

37. It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to combine the prior art elements according to known methods to yield predictable results. The prior art teaches all of the limitations of the claimed invention. It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to have humanized the murine anti-FAS CH11 antibodies taught by Jiang et al., and Caligirui et al., in a combined composition with any anti-cancer chemotherapeutic agent, such as 5-FU or its functional equivalents, oxaliplatin, irinotecan, and raltitrexed (Tomudex), as taught by Mross et al. One of ordinary skill in the art would have known that humanized antibodies are less antigenic than fully murine antibodies (see, i.e. Caligirui et al., column 5, lines 54-67) and both Jiang et al., and Caligirui et al. teach compositions comprising anti-FAS antibodies and chemotherapeutic agents. Caligirui et al. exemplifies this combination of chemotherapeutic agents by reciting anti-FAS antibodies and the chemotherapeutic agent, cisplatnin. Jiang et al., specifically recite the combination of 5-FU and the CH11 antibodies. Mross et al., teach 5-FU as functionally equivalent to the chemotherapeutics: oxaliplatin, irinotecan, and raltitrexed (Tomudex). One would have reasonably expected success because Caligirui et al. teaches that humanized antibodies are less antigenic to human subjects and the construction of humanized chimeric antibodies is routine in the art (see the ‘826 patent, column 5, 64-67 to column 6, lines 1-10). Administration of a combination of humanized anti-FAS antibodies, such as CH-11 in combination with a chemotherapeutic agent such as 5-FU or its equivalents, oxaliplatin, irinotecan, and raltitrexed (Tomudex), would have been prima facie

obvious to one of ordinary skill in the art over Jiang et al., in view of Caligirui et al. and Mross et al., which were well known in the art at the time of the instant invention. The combination of humanized anti-FAS CH-11 antibodies with a functionally equivalent chemotherapeutic agent, such as oxaliplatin, irinotecan, or raltitrexed (Tomudex) would have yielded nothing more than predictable results to one of ordinary skill in the art at the time the invention was made.

38. The instant situation is also amenable to the type of analysis set forth in In re Kerkhoven,205 USPQ 1069 (CCPA 1980) wherein the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to for a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art.

Provisional Non-Statutory Double Patenting Rejection

39. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a

nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

40. Claims 18-25 and 27-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18, 19, 23, 24, 26, 30, 31, and 33 of copending Application No. 10/514,604. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 18-25, and 27-33 in the instant application are drawn to the same subject matter as those of instant claims 18, 19, 23, 24, 26, 30, 31, and 33 in application 10/514,604. Both sets of claims are drawn to a composition comprising an anti-FAS antibody, wherein the anti-FAS antibody is CH-11, and a chemotherapeutic agent that inhibits topoisomerase I. Irinotecan (CPT11), as set forth in the instant claims, is a topoisomerase I inhibitor.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

41. Claims 18-34 are rejected.

42. No Claims are allowed.

43. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Thursday, 9:30AM-7:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643